Attorney Docket No. 9233-8DV3 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Ekwuribe et al.
Filed: concurrently herewith
Serial No.: to be assigned

For: *Methods of altering the binding affinity of a peptide to its receptor*

Date: November 19, 2003

Mail Stop PATENT APPLICATION
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT CITATION UNDER 37 C.F.R. § 1.97

Sir:

Attached are eight sheets of form PTO-1449 as submitted in parent application Serial No. 09/134,803, filed August 14, 1998, with the parent application number, Attorney Docket number and filing date crossed out and the current Attorney Docket number written in. Also attached is a form PTO-1449, providing a list of documents 1-3, previously made of record in application serial number 09/430,735, which is a sister divisional application of the present application that also claims priority to parent application serial number 09/134,803. Because the above-referenced references have already been made of record in these related applications, a copy of each of these references is not provided herein. However, applicants will provide a copy of any such reference cited herein upon request from the Examiner. Also included as item 4 is a reference not previously made of record, and a copy is enclosed. Applicants respectfully request that these documents be considered by the Examiner and officially made of record in accordance with the provisions of 37 C.F.R. §1.97 and Section 609 of the MPEP.

No fee is believed due. However, the Commissioner is hereby authorized to charge any deficiency or credit any refund to Deposit Account No. 50-0220.

Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop PATENT APPLICATION, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Cathy A. Schetzina

FORM PTO-1449 US Dept. of Commerce Patent and Trademark Office	ATTORNEY DOCKET NO. ~~4012-113~~ 9233.80V3	SERIAL NO. To be assigned ~~09/134,803~~
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)	APPLICANT Nnochiri N. Ekwuribe, et al.	
	FILING DATE ~~August 14, 1998~~ Concurrently herewith	GROUP ~~1646~~

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,693,769	02 Dec 1997	Kahne et al.	536	5	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO

OTHER DOCUMENTS (Including Author, Title, Journal-Date, Page Number, Etc.)

Continue on Page __

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	AA	Delgado et al. "The Uses and Properties of PEG-Linked Proteins". *Critical Review in Therapeutic Drug Carrier Systems*, 9(3, 4):249-304 (1992).

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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	5,932,462	Aug. 3, 1999	Harris et al.	435	188	

FOREIGN PATENT DOCUMENTS

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EXAMINER INITIAL		PATENT NUMBER	ISSUE DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,585,754	29 Apr. 1986	Meisner et al.			
	AB	4,179,337	18 Dec. 1979	Davis et al.			
	AC	4,003,792	18 Jan. 1977	Mills et al.			
	AD	4,849,405	18 Jul. 1989	Ecanow			
	AE	5,013,556	7 May 1991	Woodle et al.			
	AF	4,963,367	16 Oct. 1990	Ecanow			
	AG	4,044,196	23 Aug. 1977	Hüper et al.			
	AH	4,717,566	5 Jan. 1988	Eckenhoff et al.			
	AI	4,698,264	6 Oct. 1987	Steinke			
	AJ	4,684,524	4 Aug. 1987	Eckenhoff et al.			
	AK	4,410,547	18 Oct. 1983	Ueno et al.			
	AL	3,256,153	14 Jun. 1966	Heimlich			
	AM	4,935,246	19 Jun. 1990	Ahrens			
	AN	4,797,288	10 Jan 1989	Sharma et al.			
	AO	4,744,976	17 May 1988	Snipes et al.			
	AP	5,055,304	8 Oct. 1991	Makino et al.			
	AQ	5,055,300	8 Oct. 1991	Gupta			
	AR	4,772,471	20 Sep. 1988	Vanlerberghe et al.			
	AS	5,093,198	3 Mar. 1992	Speaker et al.			
	AT	4,840,799	20 Jun. 1989	Appelgren et al.			
	AU	4,622,392	11 Nov. 1986	Hong et al.			
	AV	5,653,987	5 Aug. 1997	Modi et al.			
	AW	5,792,834	11 Aug. 1998	Hakimi et al.			
	AX	5,595,732	21 Jan. 1997	Hakimi et al.			
	AY	5,539,063	23 Jul. 1996	Hakimi et al.			

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	AZ	5,559,213	24 Sep 1996	Hakimi et al.			
	BA	5,747,646	5 May 1998	Hakimi et al.			
	BB	5,286,637	15 Feb. 1994	Veronese et al.			
	BC	5,631,263	20 May 1997	Portoghese et al.			
	BD	5,602,099	11 Feb. 1997	Schiller			
	BE	5,545,719	13 Aug. 1996	Shashoua et al.			
	BF	5,641,861	24 Jun. 1997	Dooley et al.			
	BG	5,663,295	2 Sep. 1997	Moreau et al.			
	BH	5,786,447	28 Jul. 1998	Schiller et al.			
	BI	4,939,174	3 Jul. 1990	Shashoua			

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	BJ	WO93/01802	4 Feb. 1993	PCT/Switzerland				X

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	BK	Conradi, R.A., et al., "The Influence of Peptide Structure on Transport Across Caco-2 Cells," Pharm. Res., 1991, 8 (12): pp. 1453-1459.
	BL	Boccu, E. et al., "Pharmocokinetic Properties of Polyethylene Glycol Derivatized Superoxide Dismutase," Pharm. Res. Comm., 1982, 14: pp. 11-120.
	BM	Igarashi, R. et al., "Biologically Active Peptides Conjugated with Lecithin for DDS" Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater. 1990, 17: pp. 367-368.
	BN	Taniguchi, T. et al., "Synthesis of Acyloyl Lysozyme and Improvement of its Lymphatic Transport Following Small Intestinal Administration in Rats," Proceed. Intern. Symp. Control. Rel. Bioactiv. Mater., 1992, 19: pp. 104-105.
	BO	Russell-Jones, G. J., "Vitamin B12 Drug Delivery," Proceed. Intern. Symp. Control. Rel. Bioactive. Mater., 1992; 19: pp. 102-103.
	BP	Baudys, M. et al., "Synthesis and Characteristics of Different Glycosylated Derivatives of Insulin," Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater., 1992, 19: pp. 210-211.
	BQ	Chien, Y. W., Novel Drug Delivery Systems, pp. 678-679, Marcell Deffer, Inc., New York, NY, 1992.

Continued on page 3

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	BR	Pardridge, W.M., "CNS Drug Design Based on Principles of Blood-Brain Barrier Transport," J. Neurochem., 1998, 70 (5): pp. 1781-1792.
	BS	Kroll, R.A., et al., "Outwitting the Blood-Brain Barrier for Therapeutic Purposes: Osmotic Opening and Other Means," 1998 Neurosurgery, 42 (5): pp. 1083-1100.
	BT	Pardridge, W.M., "Blood-Brain Barrier Peptide Transport and Peptide Drug Delivery to the Brain," Amer. Chem Soc. 1995, pp: 265-296.
	BU	Banks, W.A., et al., "Passage of Peptides Across the Blood-Brain Barrier: Pathophysiological Perspectives," Life Sciences, 1996, 59 (23), pp: 1923-1943.
	BV	Fix, J.A., "Oral Controlled Release Technology for Peptides: Status and Future Prospects," Pharm. Res., 1996, 13 (12): pp: 1760-1763.
	BW	Terasaki, T., et al., "Oligopeptide Drug Delivery to the Brain," Amer. Chem. Soc. 1995, pp: 297-316.
	BX	Bodor, N., et al., "Molecular Packaging. Peptide Delivery to the Central Nervous System by Sequential Metabolism," Amer. Chem. Soc., 1995, p:317-337.
	BY	Nestor, J., "Improved Duration of Action of Peptide Drugs," Amer. Chem Soc. 1995, pp:449-471.
	BZ	Santiago, N. et al., "Oral Immunization of Rats with Influenze Virus M Protein (M1) Microspheres," Proceed. Intern. Symp. Cont. Rel. Bioactiv. Mater., 1992, 19: pp. 116-117.
	CA	Banting, R. G., et al., "Pancreatic Extracts in the Treatment of Diabetes Mellitus," The Canadian Med. Assoc. J. 1922, 12: pp. 141-146.
	CB	Brange, J. et al., "Chemical Stability of Insulin. 1. Hydrolytic Degradation During Storage of Pharmaceutical Preparations," Pharm. Res., 1992, 9 (6): pp. 715-726.
	CC	Nucci, et al., "The Therapeutic Value of Poly(ethylene glycol) - Modified Proteins," Ac. Drug. Del. Rev. 1991, 6: pp. 133-151.
	CD	Brange, J. et al., "Chemical Stability of Insulin. 2. Formation of Higher Molecular Weight Transformation Products During Storage of Pharmaceutical Preparations," Pharm. Res., 1992, 9 (6): pp. 727-734.
	CE	Robbins, D. C. et al., "Antibodies to Covalent Aggregates of Insulin in Blood of Insulin-Using Diabetic Patients," Diabetes, 1987, 36: pp. 838-841.
	CF	Maislos, M. et al., "The Source of the Circulating Aggregate of Insulin in Type I Diabetic Patients is Therapeutic Insulin," J. Clin. Invest., 1986, 77: pp. 717-723.
	CG	Ratner, R. E. et al., "Persistent Cutaneous Insulin Allergy Resulting from High-Molecular Weight Insulin Aggregates," Diabetes, 1990, 39: pp. 728-733.
	CH	Oka, K. et al., "Enhanced Intestinal Absorption of a Hydrophobic Polymer-Conjugated Protein Drug, Smancs, in an Oily Formulation," Pharm. Res., 1990, 7 (8): pp. 852-855.
	CI	Saffran, M. et al., "A New Approach to the Oral Administration of Insulin and Other Peptide Drugs," Science, 1986, 233: pp. 1081-1084.
	CJ	Abuchowski, A. and F. F. Davis, "Soluble Polymer-Enzyme Adducts," pp. 368-383, Enzymes as Drugs, J. S. Holcenberg, John Wiley, 1981.
	CK	Akiyama, M. et al., "The Synthesis of New Derivatives of 1-β-D-Arabinofuranosylcytosine," Chem. Pharm. Bull., 1978, 26(3): p. 981.
	CL	Gish, D. T. et al., "Nucleic Acids. 11. Synthesis of 5'-Esters of 1-β-D-Arabinofuranosylcytosine Possessing Antileukemic and Immunosuppressive Activity," J. Med. Chem., 1971, 14(12): pp. 1159-1162.

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	CM	Baker, D. C. et al., "Prodrugs of 9-β-D-Arabinofuranosyladenine. 1. Synthesis and Evaluation of Some 5'-(O-Acyl) Derivatives," J. Med. Chem., 1978, 21(12): pp. 1218-1221.
	CN	Hostetler, K. Y. et al., "Synthesis and Antiretroviral Activity of Phospholipid Analogs of Azidothymidine and Other Antiviral Nucleosides," The Journal of Biological Chemistry, 1990, 265(11): pp. 6112-6117.
	CO	Hong, C. I. et al., "Nucleoside Conjugates. 7. Synthesis and Antitumor Activity of 1-β-D-Arabinofuranosylcytosine Conjugates of Ether Lipids," J. Med. Chem., 1986, 29: pp. 2038-2044.
	CP	Aoshima, M. et al., "N^4-Behenoyl-1-β-D-Arabinofuranosylcytosine as a Potential New Antitumor Agent," Cancer Research, 1977, 37: pp. 2481-2486.
	CQ	Zalipsky, S. et al., "Attachment of Drugs to Polyethylene Glycols," Eur. Polym. J., 1983, 19(12): pp. 1177-1183.
	CR	Tsuzuki, N., et al., "Rabid Communication. Adamantane as a Brain-Directed Drug Carrier for Poorly Absorbed Drug: Antinociceptive Effects of [D-Ala^2] Leu-Enkephalin Derivatives Conjugated with the 1-Adamantane Moiety," Biochemical Pharmacology, 1991, 41 (4): pp. R5-R8.
	CS	Wagner, J., et al., "Neuropharmacology of Endogenous Opioid Peptides," Psychopharmacology: The Fourth Generation of Progress, 1995, pp: 519-529.
	CT	Horvat, J., et al., "Synthesis and Biological Activity of [Leu^5] Enkephalin Derivatives Containing D-Glucose," J. Peptide Protein Res., 1988, 31, pp: 499-507.
	CU	Shashoua V.E., et al., "γ-Aminobutyric Acid Esters. 1. Synthesis, Brain Uptake, and Pharmacological Studies of Aliphatic and Steroid Esters of γ-Aminobutyric Acid," J. Med. Chem., 1984, 27 (5), pp: 660-664.
	CV	Brewster, M., et al., "Tissue Distribution of LY231617, an Antioxidant with Neuroprotectant Activity, in the Rat," J. Pharm. Studies," 1995, 84 (7), pp: 791-793.
	CW	Chen, C., et al., "Extensive Biliary Excretion of the Model Opioid Peptide [D-$PEN^{2,5}$] Enkephalin in Rats," Pharm. Res. J., 14, pp: 345-350.
	CX	Bodor, N., et al., "A Strategy for Delivering Peptides into the Central Nervous System by Sequential Metabolism," Science, 1992, 257, pp: 1698-1702.
	CY	Sim, L., et al., "In vitro Autoradiography of Receptor-Activated G Proteins in Rat Brain by Agonist-stimulated Guanylyl 5'-[γ[^{35}S]thio]-Triphosphate Binding," Proc. Natl. Acad. Sci., USA, 1995, 92, pp: 7242-7246.
	CZ	Weber, S.J., et al., "Whole Body and Brain Distribution of [^{3}H]Cyclic [D-PEN^2, D-PEN^5] Enkephalin after Intraperitoneal, Intravenous, Oral and Subcutaneous Administration," J. Pharm. Exper. Ther., 1992, 263 pp: 1308-1316.
	DA	Alyautdin, R.N., "Delivery of Loperamide Across the Blood-Brain Barrier with Polysorbate 80-Coated Polybutylcyanoacrylate Nanoparticles," Pharm. Res. J., 1997, 14, pp: 325-328.
	DB	Chiou, G.C.Y., et al., "Systemic Delivery of Enkephalin Peptide through Eyes," Life Sciences, 1988, 43, pp: 509-514.
	DC	Sakaeda, T., et al., "Conjugation with L-Glutamic Acid for Brain Drug Delivery," Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 1966, 23, pp: 607-608.

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	DD	Chun., W., et al., "Transmucosal Delivery of Methionine Enkephalin. I: Solution Stability and Kinetics of Degradation in Various Rabbit Mucosa Extracts," J. Pharm.Sci., 1993, 82 (4), pp: 373-378.
	DE	Brewster, M.E., et al., "Efficacy of a 3-Substituted Versus 17-Substiturted Chemical Delivery System for Estradiol Brain Targeting," J. Pharm. Sci., 1994, pp: A-E.
	DF	Mosnaim, A.D., et al., "Studies of the in Vitro Human Plasma Degradation of Methionine-Enkephalin," Gen. Pharmac., 1988, 19 (5), pp: 729-733.
	DG	Weber, S.J., et al., "Distribution and Analgesia of [^{3}H][D-PEN^2, D-PEN^5] Enkephalin and Two Halogenated Analogs after Intravenous Administration," J. Pharm. Exper. Ther., 1991, 259, pp: 1109-1112.
	DH	Brewster, M.E., et al., "Effect of Molecular Manipulation on the Estrogenic Activity of a Brain-Targeting Estradiol Chemical Delivery System," J. Med. Chem., 1994, 37, pp: 4237-4244
	DI	Pardridge, W.M., "New Approaches to Drug Delivery Through the Blood-Brain Barrier," Trends in Biotechnology, 1994, pp: 239-245.
	DJ	Shashoua, V.E., et al., "N-Docosahexaenoyl, 3 Hydroxytyramine: A Dopaminergic Compound that Penetrates the Blood-Brain Barrier and Suppresses Appetite," Life Sciences, 58 (16), pp: 1347-1354.
	DK	Gibson, A.M., et al., "Specificity of Action of Human Brain Alanyl Aminopeptidase on Leu-Enkephalin and Dynorphin-Related Peptides," Neuropeptides, 1989, 13. pp: 259-262.
	DL	Prokai-Tatrai, K., et al., "Brain-Targeted Delivery of a Leucine-Enkephalin Analogue by Retrometabolic Design," J. Med. Chem, 1996, 39 (24).

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Substitut form 1449A/PTO				Compl te if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Application Number	To be assigned
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				First Named Inventor	Ekwuribe
(use as many sheets as necessary)					
Sheet	1	of	1	Attorney Docket Number	9233.8DV3

U.S. PATENTS AND PATENT PUBLICATIONS					
Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
	1.	5,061,691		Yagi et al.	10-29-1991
	2.	5,428,128		Mensi-Fatthoi et al.	06-27-1995
	3.	6,309,633		Ekwuribe et al	10-30-2001

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OTHER NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
	4.	Anderson et al. "Structure-Activity Relationship Assessment of Conjugated Enkephalins in Centrally Mediated Analgesia" *Soc. Neurosci. Abstr.* 25(1):180 (1999)	

Examiner Signatur		Date Consider d	

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